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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,379	01/09/2002	Jonathan Luke Heeney	294-105PCTUS	1582

7590 05/13/2003
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EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,379

Applicant(s)

Heeney et al

Examiner

Mosher

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/14/03.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29 and 33-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29 and 33-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

In view of the amendment and arguments filed April 14, 2003, the rejections of claims 29 and 33-44 over Ertl, alone or in combination with Pachuk, is withdrawn. On reconsideration, applicant's argument re hindsight reconstruction of the combination of Ertl and Pachuk et al, is convincing.

However, the claims are not allowed because of the following new grounds of rejection.

Claim Rejections - 35 USC § 112

Claims 29 and 33-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 recites "a first vaccine composition comprising said antigen and a first vector...." This recitation would normally be understood as meaning a composition containing a mixture of an antigenic substance (e.g. a protein) and a vector. However, it appears that the actual intent is not three mixtures of one protein with three different vectors, but three different vectors all encoding the same antigen. Therefore the claim language is confusing. It also is not clear how one would achieve the goal of "inducing or stimulating a T-helper cell response" using a mixture of protein with three different nucleic acids. It is suggested that the claims be amended to recite "comprising a first vector encoding said antigen...", etc., to better describe the invention.


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In addition, claim 33 now depends from a canceled claim. Also, since the base claim now recites a plurality of vectors, "said vector" in claims 41-43 no longer has a clear antecedent

Claim Rejections - 35 USC § 102

Claim 44 remains rejected under 35 U.S.C. 102(e) as being anticipated by Ertl 6,210,663, for reasons of record. This claim was not amended.

Claims 29 and 33-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Davis et al 6,511,845. See for example Treatment Regimens 1 and 3 at columns 9 and 10, where three different adenoviral vectors were administered sequentially for the purpose of inducing an immune response to a lentivirus antigen. Although the reference is silent upon the vectors inducing T-helper cell response, acting as an adjuvant, directing the response towards Th1 or Th2 type responses, and encoding immune response inhibitory proteins, these are all inherent characteristics of adenoviral vectors. As evidence of these inherent characteristics of adenoviral vectors, see for example van Ginkel et al, Arribillaga et al, Jullard et al, or Fields et al regarding T helper cell responses; Papp et al regarding directing the immune response to Th1 and/or Th2 type responses (as indicated by IgG1 or IgG2a levels); Russell, Mahr et al, or Burgert et al regarding immune response inhibitory proteins (such as E1a) encoded by adenovirus vectors. Therefore, although the reference does not explicitly teach all of the characteristics recited in the claims, there is reason to believe that the vectors used by Davis inherently possessed the characteristics recited in the claims. Therefore there is reason to believe that the reference meets each and every claim limitation, even those limitations not explicitly taught in the reference.



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Claim Rejections - 35 USC § 103

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as obvious over Davis et al 6,511,845. Davis discloses treatment regimens that three different vectors as sequential immunogens to produce an immune response against an antigen. Although Davis does not disclose “kits” *per se*, packaging reagents to be used together in the form of kits is conventional and done for reasons of convenience and economy and would have been obvious over Davis.

Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chamberlain et al WO 97/06632. Chamberlain discloses “the use of at least two different recombinant vectors expressing the same tumor-associated antigen for immunizing and boosting vaccinations for active treatment of malignant disease.” The recitation “at least two” reasonably suggests three. Chamberlain differs from the claimed invention in that Chamberlain does not disclose “kits” *per se*. However, packaging reagents to be used together in the form of kits is conventional and done for reasons of convenience and economy and would have been obvious over Chamberlain. It is noted that the instant claims recite the intended use “for stimulating a T-helper cell response”, and Chamberlain discusses CTL responses. However, the kits, as claimed, encompass the same vectors as disclosed in Chamberlain, and therefore it is concluded that a kit containing the different vectors of Chamberlain would have been obvious, even if Chamberlain taught a different intended use for the combination of vectors.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 12, 2003

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600